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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,052	09/12/2001	Josef Pitha		9900

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EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/950,052

Applicant(s)

PITHA ET AL.

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 15-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The RCE Request and amendment received 3/7/05 have been entered and claims 1, 15-22 are currently pending in this application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 15-22 are rejected under 35 U.S.C. 102(b) as being anticipated by

Nutrition Reviews.

Nutrition Reviews entitled "Absorption and Effect of Ingested Mannoheptulose" teaches on page 206, the capacity of mannoheptulose to induce temporary hyperglycemia is known. The secretion and synthesis of insulin is inhibited by mannoheptulose. On page 207, mannoheptulose may be a therapeutic agent for treating hypoglycemic conditions.

Applicant's arguments filed 3/7/05 have been fully considered but they are not persuasive.

Applicants argue the reference does not teach beneficial biological results seen in caloric restriction, only treating hypoglycemia based on fasting administration.

It is the examiner's position the specification teaches the criteria for mimicking caloric restriction is reducing insulin, which would raise glucose levels. Raising glucose levels is taught by Nutrition Reviews. Further, no beneficial biological results are claimed.

Claims 1, 15-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The addition to the claims of the negative limitation of "without reliance on food deprivation" is not found in the present specification as originally filed.

Example II on pages 8-9 of the specification, newly added to this CIP application, discloses dogs were fed a standard diet throughout the study period, but how much food they ate relative to normal before and after administration is not disclosed. Small changes in ingested food may have significant effects over time.

Claims 1, 15-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The present claims are directed to mimicking caloric restriction without reliance on food deprivation by administering mannoheptulose. Some of the beneficial results of caloric restriction may include longer life span, improved health in old age, and loss of body weight. No written description is found for any benefits of caloric restriction obtained by the claimed method.

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Doses of mannoheptulose were administered according to body weight in Example II but how many times the mannoheptulose was administered per unit time is not set forth. No data is shown. It would appear insulin was measured and was decreased by the mannoheptulose but the statistical significance of this effect or its results are not seen.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 1 is directed to mimicking caloric restriction without reliance on food deprivation. What may be intended by mimicking caloric restriction is unclear and is not defined in the specification. Claim 1 does not state any amount or dose of mannoheptulose is administered. In claim 15 it would not appear likely a dose of 0.001 g/kg would be effective. In claim 18 "the animal" lacks antecedent basis. Claim 20 fails to further limit the claims it depends from.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ohkuma (5,344,824) teaches reducing insulin.

Chapnick (US 2004/0228933 A1 and US 2003/0092669 A1) teach normalizing insulin with mannoheptulose.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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